

"Members are reminded to disclose any changes in Conflict of Interest (COI) information since the most recent disclosure and follow all COI policies."

Clinical Standards Committee Roll Call | Attended | Did Not Attend

| | | | | | |
|----------------------|--|-------------------------------------|----------|---------------------------|-------------------------------------|
| Co-Chair | Joseph Taylor, MD, PhD | <input checked="" type="checkbox"/> | Co-Chair | Saydra Wilson, MD | <input checked="" type="checkbox"/> |
| Member | Scott Aaronson, MD | <input checked="" type="checkbox"/> | Member | Rebecca Allen, MD, MPH | <input checked="" type="checkbox"/> |
| Member/ VP | Tracy Barbour, MD | <input checked="" type="checkbox"/> | Member | Daniel Blumberger, MD | <input checked="" type="checkbox"/> |
| Member | Suneel Chamoli, MBBS, MD, FRANZCP | <input type="checkbox"/> | Member | Pilar Cristancho, MD | <input checked="" type="checkbox"/> |
| Member | Andrew Kozel, MD, MSCR, DFAPA, FCTMSS | <input checked="" type="checkbox"/> | Member | Dino Santoro, MD | <input checked="" type="checkbox"/> |
| Member | Subha Subramanian, MD | <input checked="" type="checkbox"/> | Member | Rick Trautner, MD, FCTMSS | <input checked="" type="checkbox"/> |
| Non-Voting Member | Linday Oberman, MD | <input checked="" type="checkbox"/> | | | |
| President | Joshua Brown, MD, PhD | <input checked="" type="checkbox"/> | | | |

Guests & Staff: None

I. Dr. Taylor called the meeting to order at 2:02 pm (ET)

II. Review November meeting minutes

The Committee reviewed the minutes.

There was a motion to approve the November 13, 2025 meeting minutes, Seconded, Approved.

III. Unfinished Business

A. Review of statements on the website

- Reviewed statement edits.
- Getting insurance coverage for TMS/OCD edited by Dr. Santoro.
 - From November, 2020. Article is outdated and not created using the current CTMSS statement process.
 - Discussion centered on who has authority to decide if statements remain published.
 - Insurance Committee can provide input, but ultimately the decision likely belongs to the Executive Committee.
 - General direction:

The Clinical TMS Society

Clinical Standards Committee Meeting Minutes

December 11, 2025 @ 2pm ET / 1pm CT / 12pm MT / 11am PT

Friday, December 12, 2025 @ 6am AEDT

Via Zoom

- Notify the Executive Committee and ask if non-committee statements are allowed on the website. If they are, ask the Insurance Committee to review this statement. If not, archive/remove the statement.

ACTION – Dr. Barbour will make sure this is on the Executive Committee's agenda.

ACTION – Dr. Taylor will email Carlene MacMillan about the statement and next steps.

- Guidelines for training and monitoring of TMS treaters edited by Dr. Wilson.
 - Removed references to an ethics document not yet completed.
 - Committee confirmed alignment with Trap guidelines.
 - Update the review date at the bottom.

There was a motion to approve the revised guidelines for training and monitoring of TMS treaters, Seconded, Approved.

ACTION – Continue edit review at the next meeting.

B. Statement of concern regarding One-D accelerated TMS protocols

- Reviewed draft. Discussion points:
 - Direct-to-Consumer (DTC) Advertising
 - Wording revised to state the Society discourages DTC advertising of interventions lacking sufficient evidence.
 - FDA Clearance Clarification
 - Important to counter misleading commercial claims that "One-D is FDA cleared."
 - Committee clarified:
 - FDA clears devices, not protocols.
 - The One-D protocol itself is not included in FDA instructions for use.
 - Statement was edited to assert this plainly without excessive technical detail.
 - Evidence Base
 - Committee aligned on the following:
 - Evidence for One-D protocol consists of one small, open-label, retrospective case series.
 - Findings have not been replicated.

- Statement to avoid implying randomized trials are the only acceptable form of evidence.
- Conclusion strengthened to underscore:
 - Current low level of evidence.
 - Inappropriateness of DTC advertising for One-D.
 - Need for caution in clinical use.

There was a motion to approve the One-Day statement of concern, Seconded, Approved.

ACTION – After Executive Committee decision, Dr. Wilson will contact the CTMSS journal for publication in the CTMSS section of the journal.

No decision was made to publish the statement on the website, social media, or newsletter.

IV. New Business

A. Committee members are reminded to submit needed documentation to continue committee service through the 2026-2027 committee year by December 31, 2025.

- See email sent from Jessi Maurer on 11/10/2025 for instructions and document links.

V. Committee Projects and Informational Items

A. Statement on appropriate advertising and ongoing list of articles of concern for the website

- No time for a report. Deferred to next meeting.

B. Create guidelines for repeat MT's

- No time for a report. Deferred to next meeting.

C. Review of literature on treatment extension

- No time for a report. Deferred to next meeting.

D. Statement on TMS and pregnancy

- Reviewed draft. Discussion points:
 - Purpose should be sharpened:

- Emphasize that TMS is a reasonable treatment option in pregnancy based on available safety evidence.
- Condense into a high-level statement.
- Move detailed safety and registry data to footnotes.
- Conclusion should stress:
 - This is a protected population that is difficult to study.
 - Available evidence suggests safety but remains limited.

ACTION – Dr. Cristancho will revise the statement based on the Committee's feedback.

E. Device Clearance Table Task Force

- No time for a report. Deferred to next meeting.

VI. Adjourn Meeting at 3:01pm (ET)

VII. **Next Meeting:** Thursday, January 8, 2026 @ 2pm ET / 1pm CT / 12pm MT / 11am PT / Friday, January 9, 2026 @ 6am AEDT

2025-2026 Committee Goals:

- Create guidelines for repeat MT's. *In progress*
- Consider treatment extension review of literature. *In progress*
- Develop a procedure for rapid communication between Clinical Standards and Insurance Committees. *In progress*
- Follow up on the TMS pregnancy registry and consider a statement. *In progress*
- Evaluate TMS evidence for bipolar depression and consider a statement. **Tabled until more evidence is available**
- Evaluate TMS evidence after ECT non-response and consider a statement. **Tabled until more evidence is available**
- Revisit statement policies and processes. *In progress*